JUL 14 2008

510(k) SUMMARY
ConMed Linvatec Bio Mini-Revo Suture Anchor

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for the 510(k) Number K072291.

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Jon Ward
Regulatory Consultant
Telephone: 813-645-2855
FAX: 813-645-2856

C. Device Name

Trade Name:	*ConMed Linvatec Bio Mini-Revo Suture Anchor*
Common Name:	Bioabsorbable suture anchor
Classification Names:	Biodegradable soft tissue fixation fastener
Proposed Class:	Class II
Product Code:	MAI
Regulation:	21 CFR Part 888.3030

D. Predicate/Legally Marketed Devices

The predicate/legally marketed devices for the Bio Mini-Revo are:

Device name:	Bio Mini-Revo
Company name:	ConMed Linvatec
510(k) #:	K053561

K072291 #2/2

510(k) Summary
ConMed Linvatec Bio Mini-Revo Suture Anchor
June 30, 2008

Device name:	Bio-FASTak Suture Anchor
Company name:	Arthrex
510(k) #:	K061863

E. Device Description

The Linvatec Bio Mini-Revo® suture anchor is a bioabsorbable screw-in suture anchor that is preloaded on a disposable inserter device with one non-absorbable, braided, polyethylene suture. The Bio Mini-Revo® suture anchor is manufactured from Self-Reinforced (96L/4D) PLA Copolymer. The Copolymer is inert and non-collagenous through the absorption process. The device will be available in two versions; with or without colorant D&C violet #2.

F. Intended Use

The Bio Mini-Revo Suture Anchor is intended to reattach soft tissue to bone in arthroscopic or open hip procedures; such as acetabular labral repair.

G. Substantial Equivalence

The ConMed Linvatec Bio Mini-Revo Suture Anchor is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the identified predicate devices, K053561 and K061863.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ConMed Linvatec
% Mr. Jon Ward
11311 Concept Boulevard
Largo, FL 33773-4908

JUL 14 2008

Re: K072291
Trade/Device Name: ConMed Linvatec Bio Mini-Revo Suture Anchor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, JDR, HWC
Dated: June 30, 2008
Received: July 2, 2008

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072291

Device Name: ConMed Linvatec Bio Mini-Revo Suture Anchor

Indications for Use:

The Bio Mini-Revo Suture Anchor is intended to reattach soft tissue to bone in arthroscopic or open hip procedures; such as acetabular labral repair.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072291